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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,684	05/04/2006	Andreas Hefel	RBL0109-01	7978

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BAKER & DANIELS LLP
111 E. WAYNE STREET
SUITE 800
FORT WAYNE, IN 46802

EXAMINER	
ML, QIUWEN	
ART UNIT	PAPER NUMBER
1655	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/595,684	HEFEL, ANDREAS	
	Examiner	Art Unit	
	QIUWEN MI	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-24,28 and 31-44* is/are pending in the application.

4a) Of the above claim(s) *31-41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-24,28 and 42-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment in the reply filed on 7/27/09 is acknowledged, with the cancellation of Claims 1-21, 25-27, 29-30; and the additional newly added Claims 42-44. Claims 22-24, 28, and 31-44 are pending. Claims 31-41 are withdrawn from further consideration. **Claims 22-24, 28, and 42-44 are examined on the merits**.

Any rejection that is not reiterated is hereby withdrawn.

Claim Rejections –35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 22-24, and 28 remain rejected, Claims 42-44 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Shibata (EP 835654 A1), in view of Ron et al (US 5,122,367), and further in view of Shefer et al (US 2003/0195133).

This rejection is maintained for reasons of record set forth in the Office Action mailed out on 1/26/09, repeated below, slightly altered to take into consideration Applicant's amendment filed on 7/27/09. Applicants' arguments filed have been fully considered but they are not deemed to be persuasive.

Shibata teaches a method of producing a pharmaceutical preparation with sustained effect for oral administration of a pharmacologically active ingredient, which method comprises admixing a predetermined amount of said pharmacologically active ingredient (thus a first active substance) with a predetermined amount of glucomannan (claim 4) (thus a second active substance). Glucommannan is the chief polysaccharide present in the corms of a variety of Amorphophallus plants (thus a botanical matrix of a polysaccharide). The inventor noted that glucomannan makes a very viscous solution when dissolved in water and that glucomannan is not decomposed in the small intestine but is decomposed in the large intestine by Escherichia coli and loses its viscosity. The inventor then sought the possibility of properly delaying absorption of a drug in the small intestine both by suppressing conveyance of the drug though the small intestine in the direction to the anus and suppressing diffusion of the drug in the solution (thus slowly released for resorption by the human or animal digestive system), both making use of the viscosity of the solution. As a result, the inventor has found that when glucomannan is orally administered together with a drug, gradual absorption of the drug occurred over a prolonged time period (thus increase of the nutrient-bio-availability of vital substances) compared with the case without administration of glucomannan, and that there is no reduction of overall absorption of the drug (thus separated from each other in their function) (page 2, lines 28-38). Thus, the present invention provides a pharmaceutical preparation with sustained effect for oral administration of a pharmacologically active ingredient comprising a mixture of said pharmacologically active ingredient and glucomannan (thus increase for improvement of wellbeing) (thus the embedded active substances are slowly released for resorption). In accordance with the present invention, the length of time during which the absorption of the

pharmacologically active ingredient takes place may be conveniently controlled by simply adjusting the proportion of glucomannan to the amount of the active ingredient. Thus, the present invention allows sustainment of pharmacological effect of a variety of active ingredients (thus a first active substance and a second active substance) orally administered to mammals including human (page 2, lines 38-44). Shibata further teaches the pharmaceutical preparation may be in any convenient form suitable to oral administration, such as a powder, granules, capsules, tablets, an aqueous preparation (page 3, lines 20-22).

Shibata does not teach HGH is embedded in galactomannan and/or glucomannan; neither does Shibata teach the nutritional material comprises antioxidant coenzyme Q10.

Ron et al teach a simple polysaccharide such as sucrose is used both as a stabilizer, to hinder denaturation and to increase the thermal stability of the growth hormone, and to modulate the release rate of the growth hormone from the bioerodible controlled release device. The result is an increase in the duration of release of the peptide and a decrease in initial release rate, when compared to non-stabilized composition, which permits longer and more uniform therapeutic treatment, without aggregation of the growth hormone (the same as somatotropin human growth hormone) (col 1, lines 20-30).

Shefer et al teach controlled delivery composition (see Title). Shefer et al teach the controlled release system of the invention can also contain other antioxidants including those well known in the art. Representative antioxidants include vitamin E, tocopheryl acetate, betaglucan, and coenzyme Q10 [0136].

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to adopt the procedure of using the polysaccharide to modulate the release

rate of the growth hormone from Ron et al since Ron et al teach it permits longer and more uniform therapeutic treatment. Since Glucommannan is the chief polysaccharide present in the corms of a variety of Amorphophallus plants, and it would have been obvious to adopt the procedure of using glucommannan to modulate the release rate of the growth hormone so as to increase the bioavailability of the hormone since Shibata teaches glucommannan has sustained effect for oral administration of a pharmacologically active ingredient.

It would also have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to adopt the procedure of using antioxidant coenzyme Q10 in the slowly released/control released system since Shefer et al teach the controlled release system of the invention can also contain antioxidants coenzyme Q10. Furthermore, since Shibata teaches galactomannan allows sustainment of pharmacological effect of a variety of active ingredients orally administered to mammals, one of ordinary skill in the art would have adopted the procedure of using glucomannan to sustain the pharmacological effect of antioxidant coenzyme Q10.

Since all the references yielded beneficial results in control released delivery system, one of ordinary skill in the art would have been motivated to make the modifications and combine the references together.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Applicant argues that "Current claim 22 specifies at least one nutritional additive and specifies that the active substances are separated from each other. The subject specification discloses production methods to achieve this and advantages of this arrangement. Such advantages include lack of mixing, which can cause undesired interactions between different active ingredients during manufacture, in packaging, and in the gastrointestinal tract, for example. This is discussed in paragraphs 31 and 54-55, for example, of the published specification (US 2008-0206340). Claim 42, for example, specifies two active substances. Shibata is not cited in the office action as disclosing these aspects of claim 22, and Shibata does not mention or address combinations and prevention of interaction. Likewise, Shibata does not disclose manufacturing methods for keeping such active ingredients isolated from each other. Similarly, Ron does not relate to such formulations. Ron relates to delivery of growth hormone. Shefer relates to fragrances and the like in nanospheres that burst upon heating and the like" (page 6, paragraphs 2-5 from the bottom).

This is not found persuasive. Since Shibata teaches when glucomannan is orally administered together with a drug, gradual absorption of the drug occurred over a prolonged time period (thus increase of the nutrient-bio-availability of vital substances) compared with the case without administration of glucomannan, and that there is no reduction of overall absorption of the drug, thus it is implied that it is always separated from each other in their functions. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., lack of mixing, which can cause undesired interactions between different active ingredients during manufacture, in packaging, and in the gastrointestinal tract) are not recited in the rejected claim(s). Although the

claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In addition, Ron was brought in since Ron teaches using the polysaccharide to modulate the release rate of the growth hormone as it permits longer and more uniform therapeutic treatment. Since Glucommannan is the chief polysaccharide present in the corms of a variety of Amorphophallus plants, and it would have been obvious to adopt the procedure of using glucommannan to modulate the release rate of the growth hormone so as to increase the bioavailability of the hormone since Shibata teaches glucommannan has sustained effect for oral administration of a pharmacologically active ingredient. Furthermore, Shefer et al was brought in since Shefer et al teach the controlled release system of the invention can also contain antioxidants coenzyme Q10, and since Shibata teaches galactomannan allows sustainment of pharmacological effect of a variety of active ingredients orally administered to mammals, one of ordinary skill in the art would have adopted the procedure of using glucomannan to sustain the pharmacological effect of antioxidant coenzyme Q10.

Applicant's arguments have been fully considered but they are not persuasive, and therefore the rejections in the record are maintained.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

QM

/Michele Flood/

Primary Examiner, Art Unit 1655